

May 7, 1999

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FDA (HFE-88)
5600 Fishers Lane
Rockville, MD 2085

Dear Sir or Mamma:

Please find enclosed a submission for comments on herbal regulation. Thank you for your previous efforts in regulating the alternative medicine markets.

Sincerely,

Thank You

Anonymous

98P-0169

CH

The Herbal Dilemma

A person would think that living in Boulder, the “all natural” capital of the world, would mean they know a lot about natural foods, supplements and herbs. Somehow I slipped through those “natural” cracks! I managed to live twenty years of my life without knowing anything about natural products or alternative medicines. I’m sure it had something to do with the fact that I have asthma, on top of many other things, and have always depended on the traditional doctors. At the time, the only thing to be considered a cure came from the doctor’s office. Along with the cure came the bill and bottles upon bottles of medicine. Up until a few months ago, I had never heard about the alternatives such as herbs and supplements. All the sudden I was hearing about things like Echinacea, St. John’s Wort and Ginseng. The alternatives fascinated me. It meant I could take the medicine I needed and it would cost half the price. However, I noticed there was very little information about herbs and the possible side effects. Most people I talked to said there were no side effects and everyone swore by their herbal product of choice. So I invested in a product that contained the ingredient White Oak Bark. Little did I know that White Oak Bark is what aspirin is made of; not to funny when you are allergic to aspirin. After taking the product, I could feel my heart racing and it was hard to get comfortable. When I consulted a friend and heard about the ingredient, I realized I made a wrong decision. Only there was nothing to make the decision off of. There was no information on the bottle, very little write-ups about the herbs and then I find out that none of this is required! I also learned that herbal manufacturers are not required to put anything on their labels and the FDA plays only a small role, doing studies only after people have died or a large quantity ends up in the hospital. After learning this information, I quickly went back to my prescribed cure; at least it had been approved! This incident led me to the conclusion that herbal and dietary

supplements need to be regulated for the safety of the people and to keep the manufacturers in line.

I admit, the number of deaths due to herbal supplements is very small in comparison to those caused by prescribed medicines. I believe this is due to one main reason. A person goes out into a field and picks a plant, ingests it and feels happy for the next five hours. Boom! This plant makes people happy. Soon after this revolution, a product is produced out of a garage. It is then bottled, sold and never tested by anyone else! The trick is that on the label it is called "happy maker." There are a few herbs listed on the back and no warnings or anything. So someone takes the happy pill, and thinks it makes them feel good. Truth is, it's a plant that has no proof behind it, and it was picked out of a field by a person who likes to eat plants. My point being that anyone can release an herbal product with no regulated testing behind it. This should be very alarming to society knowing that many people are substituting tested and prescribed medicine for herbal supplements with no testing. I believe that anything that falls in a medicinal category should be tested by professionals under strict regulations. I do not care about the price; it is a human life at stake! It should not matter that herbal manufactures can not afford to reproduce labels with the ingredients on them. Ingredients are what lets people know if they can or can not take something. Also, it should not matter that the testing of products is time consuming and expensive. The consumers will wait for a product that is safe and can be taken without having to wait to see if you have a reaction. Consumers have the right to all information and more important than that, the correct information. As long as producers are not required to do anything, nothing will be done!

Manufacturers have the responsibility to produce a product that is safe for people and works for their benefit. I believe there are good, honest companies out there that follow this

creed. On the other hand, there are people out there that want to capitalize on one of the largest growing markets last year. These people are smart enough to realize they can do this and no one will watch over them. For example, even though the herb Ephedra sent many people to the hospital and possibly killed others, it is still being found in herbal products. Why? Because the product does not have to be tested before hitting the shelf! And many herbal products are on the market without any warning not to take if pregnant. What about tinctures that have 44% pure grain alcohol in them without saying "do not operate heavy machinery while taking this product?" In a market that is growing so quickly because of the hype of alternatives it is not enough to say just trust the manufacturers. Once again, when it comes to a human beings safety, trust is not enough.

There are no ph.d's required to release an herbal product. No testing required, no standards to follow. A ten-year-old or an uneducated thirty five-year-old could release their concoction. A plant found in a foreign field or a flower raised in a garage can be made into a product. And the bottom line is that the end user of this is an uneducated human. It is inevitable that as the popularity of alternative medicine increases, there will be more deaths and product epidemics. Manufacturers need to have regulations to follow and a regulator watching their every move. Everything should be tested, warnings should be clearly displayed and the consumer should be educated. Why should people have to wait until someone dies to have this stuff enforced? The FDA needs to place the same regulations on herbal manufacturers as are on approved medicinal companies. Better now, before it is too late!